B ADMINISTRATIVE INFORMATION

B-1 Summary of Safety and Effectiveness Statement

B-1-1 Ref. CFR 807.92

1	Submitted by:	Danish Diagnostic Development A/S Dr. Neergaardsvej 5F 2970 Horsholm, Denmark Tel: + 45 45 768888 Fax: + 45 45 768889
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	Preparation date:	10 February 2000
2	Device Trade Name:	Unicorn
	Common Name:	Gamma Camera System
	Classification name:	Emission computed tomography system
3	Predicate Device:	GE, Phoenix Plus, & Base Nuclear Medicine Single Detector
	510(K) Number:	K951144
4	Device description:	The Unicorn system design includes an integrated patient table for whole body scanning, a collimator cart for easy collimator change and a handset enabling quick table and radial/rotate/ tilt detector positioning. The Unicorn detector tilt motion enables patients to imaged in a comfortable sitting or standing position.
	Functional description:	The detector collects incoming gamma radiation and provides position and energy output data that via the ADC board is sent to the acquisition computer for conversion, storage and display. The detector operates in the following manner. Before an acquisition starts, the acquisition computer loads calibration and tuning information into the detector. The incoming gamma ray photons are converted into visible light within the detector crystal. This light is amplified by 48 PM-tubes in the detector. The detector converts the signals from the PM-tubes and send these signal to an acquisition computer located next to the gantry. The acquisition computer processes and displays the data.

5 Intended use:

The Unicorn system is a single head system designed to acquire data for whole body and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high-resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes.
The intended use for the Unicorn is the same as for the predicate device.

6 Summary of technological characteristics:

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The device has basically the same technological characteristics as the predicate device:

	Submitted device: Unicorn	**Predicate device: Millennium**
Design:	Lightweight compact casted aluminum gantry supporting the detector in an unbalanced design. The gantry ring bore supports the middle part of the patient table.	Casted aluminum gantry supporting the detector in a balanced design by means of a counter weight.
Material:	Painted and anodized aluminum, cromated iron plate, painted lead, fiberglass covers.	Painted and anodized aluminum, cromated iron plate, painted lead, fiberglass covers.
Energy source:	Mains supply. 100VAC – 240VAC	Mains supply.
Patient Table:	The patient table is an integrated part of the gantry. The table is a U- shaped aluminum plate supported at each end by a casted aluminum end piece. Table motions; horizontal motion only.	The patient table is a separate part of the system. The table is a casted aluminum design consisting of a top part and a supporting part provided with 4 wheels for positioning. Table motions; horizontal, vertical and lateral motions.

Detector:	The detector is supported by means of 2 casted aluminum brackets secured to the side of a gantry bearing by means of 2 linear bearings. The gantry bearing enables the detector to rotate round the table. The linear bearings enables radial detector positioning and detector tilt. The detector is a reinforced casted lead housing covered by fiberglass.	The detector is supported by means of 2 steel arms in a balanced design. The 2 arms are secured to the inside of a gantry bearing enabling radial detector positioning and detector tilt. The gantry bearing enables the detector to rotate round the table The detector is a reinforced casted lead housing covered by fiberglass.
Software:	The Unicorn acquisition station is based on a PC architecture with Windows NT 4.0 SP 6+ operating system. The system is controlled by a software package formed by a dedicated Software (S/W) package for Graphic User Intreface (GUI) and a dedicated S/W package designed for the purpose of controlling system setup, gantry/table motions and acquisition.	The Millennium acquisition station is based on a PC architecture with a UNIX operating system. The system is controlled by a software package providing means for a Graphic User Intreface (GUI) and basis for the control of system setup, gantry/table motions and acquisition.

6 b Description of how the non clinical test results has been collected.

Intrinsic Spatial Resolution, FWHM, CFOV @ surface. ≤ ± 3.7mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
Spatial Resolution, FWHM, LEGP collimator @ 10cm, Tc-99m. < 10.3mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994. (section 3.5.3)
Energy Resolution, @Tc-99m. ≤ 9.4%	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
Spatial Linearity, UFOV. < ± 0.16mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
Flood Field Uniformity, UFOV Intrinsic. < ± 3.5 %	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.

Maximum Count rate @ 180k cps with scatter > 320k cps	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
Count rate Sensitivity, @ 20 % loss. > 225k cps	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
Detector Background Sensitivity, @180 °, 356 kev. < 12.0 %	The Unicorn detector was mounted with a Medium Energy General Purpose collimator (MEGP). A 356 kev source in source holder (NEMA standard fig. 2-4) was placed 10 cm in front of the collimator. With 20% symmetric energy window setting the count rate was verified (less than 10 k cps). Moving the source 360 ° around the Detector in X- and Y direction the position of the maximum count rate was found. The maximum % was calculated according to NEMA Standard NU 1-1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN 3 0 2000

Niels Sorensen
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Dr. Neergaardsvej 5F
2970 Hosholm (R)
Denmark

Re: K001888
Unicorn (SPECT) System
Dated: June 14, 2000
Received: June 15, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Sorensen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

B-2 FDA Indications for Use Form

Indications for Use Form

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510(k) Number (if known): K001888

Device Name: UNICORN

Indications For Use:

The Unicorn system is a single head system designed to acquire data for whole body static, gated or dynamic and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, Tl-201, Il-23, In-111, Ga-67, Co-57.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001888